IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Masato FUJIOKA et al.

Title: THERAPEUTIC AGENTS FOR INNER EAR DISORDERS

CONTAINING AN IL-6 ANTAGONIST AS AN ACTIVE

INGREDIENT

Appl. No.: 10/593,776

International 3/24/2005

Filing Date:

371(c) Date: 9/22/06

Examiner: Prema Maria MERTZ

Art Unit: 1646

Confirmation 4182

Number:

DECLARATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I, Simon J. Elliott, declare:

Deposits under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure have been made as follows:

The cell line which produces PM-1 antibody, deposited on July 12, 1989, with the
Fermentation Research Institute, Agency of Industrial Science and Technology, 1-3, Higashi
1-chome, Tsukuba-shi, Ibaraki-ken, 305 Japan, and accorded Accession No. FERM BP-2998.
 (The cell line was originally deposited on July 12, 1989, accorded Accession No. FERM P10839, and was then transferred to Accession No. FERM BP-2998 on July 10, 1990.)

- 2. The hybridoma cell line which produces MR16-1 antibody, deposited on March 13, 1997, with the National Institute of Bioscience and Human Technology, Agency of Industrial Science and Technology, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305 Japan, and accorded Accession No. FERM BP-5875.
- 3. The name and address of the depository institute has been changed to "the National Institute of Advanced Industrial Science and Technology, Patent and Bio-Resource Center. Chuo-6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305-5466, Japan."
- 4 Copies of the receipts of original deposits, and English translations, of the aboveidentified international deposits are submitted herewith.
- All restrictions on the availability to the public of the cultures deposited will be irrevocably removed upon the granting of a patent from the above-identified application.
- I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued therefrom.

Respectfully submitted.

Date September 30, 2008

FOLEY & LARDNER LLP Customer Number: 22428 Telephone: (202) 295-4726

Facsimile: (202) 672-5399 Simon J. Elliott, Ph.D. Attorney for Applicant

Registration No. 54,083

DEPOSITOR Name Tadamitsu Kishimoto BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

Address 5-31, Nakano-cho 3-chome, Tondabayashi-shi, Csaka 584

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR: PM1

(Deposition Number)

SITOR: PM1

FERM BP-2998

II. SCIENTIFIC DESCRIPTION AND/OR TAXONOMIC DESIGNATION The microorganism identified under I above was accompanied by: a scientific description

a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on July 12, 1989 (Date of the original deposit).

(Transferred from FERM P-10839 deposited on July 12, 1989.)

IV. INTERNATIONAL DEPOSITARY AUTHORITY

Fermentation Research Institute

Agency of Industrial Science and Technology

Director General To

Tomoo Suzuki

1-3, Higashi 1 chome, Tsukuba-shi, Ibaraki-ken, 305, Japan

July 10, 1990

	NAL RECOGNIT	ION OF THE DEPOSIT OF
		MS FOR THE PURPOSES OF
(特許手法上の数生物の気託の直線的承認)	PATENT PROCE	DURE .
し に関するプダベスト系的		
		HE CASE OF AN ORIGINAL
下記回答寄託当局によって規則7. 1に従い	DEPOSIT	
下記四岸会に当めによって次時 1. 1に依い 発行される		
≆(1∈tro		ant to Rule 7, 1 by the L DEPOSITARY AUTHORITY
原客託についての受託証		t the bettem of this
Majacic IV COXILL	page,	
氏名 (名称)	岸本 忠三	
SHS		毁
あて名 🕣 584	- 270 2 - 2	
大阪府軍田林市中野町	131825316	
1. 聯生物の表示		
(寄託客が付した規則のための表示)		(묫託등등)
PMI		数工研究研究 · 2998 号
•		(FERM BP- 2998).
□ 科学的法 気及び分類学上の位置		. ,
· 「猫の斑生物には、次の享項を記載した文者が表作	すされていた,	
□ 科学的性景		
─────────────────────────────────────		
回、 受領及び受抗・		
本田探奇氏当局は、平成 元年 7月12日 (原	(病託日) に受領した 1 倍	
・ ・		
V. 田松客託当局		32,3927
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通篇是案名工業技術	民风左闭工系技	初班交列
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所長的木質經濟經濟		
Tomoo (Style A. D.	. DIRECTOR C	ENERAL
あて3: 日本回茨投票つくは市耳	178153	要(数据数字3105)
1-3. Higashi I chone Tsubi		
	JAPAN	

BUDAPEST TREATY ON THE INTERNATIO-

平成 2年 (1990) 7月 10日

特許手続上の微生物の奇託の国際的承認 に関するプタペスト条約

BUDAPEST TREATY ON THE INTERNATIO-NAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

下記国際客託当局によって規則7.1に従い 発行される。

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

原客託についての受託証

issued pursuant to Rule 7, 1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

氏名(名称)

中外型栗株式会社

殿

套託者

取締役社長 永山 治

あて名 115 東京都北区評問5丁目5番1号

1. 俗牛物の表示

(客託者が付した識別のための表示)

Rat-mouse hybridoma MR16-1

(受託番号)

FERM BP- 5875

2. 科学的性質及び分類学上の位置

1 棚の器生物には、次の事項を記載した文書が添付されていた。

- 醫 科学的性質
- 分類学上の位置

3. 号值及び受託

太同縣套新出席は、 平成 9年 3月13日 (原套託日) に受領した1棚の後生物を受託する。

4. 移管請求の受領

本国際寄託当局は、

日 (原寄託日) に1 棚の微生物を受領した。

日 に原杏託よりブダベスト条約に基づく杏託への移管請求を受領した。

そして、 5. 國際客託当局

通商産業省工業技術院生命工学工業技術研究所

National Institute of Bioacience and Human-Technology

名 称:

Agen (工業が付金のです。) Science and Technology (一書の中間) (日本の中間) (日本の中国) (日本の あて名: 日本 国 天 第5年では 市東 1 丁 目 1 番 3 号 市東1丁目1番3号(単位番号305)

305. JAPAN

平成 9年 (1997) 3月13日

Depositor

Name: CHUGAI SEIYAKU

KABUSHIKI KAISHA Representative: Osamu Nagayama

Address: 5-1, Ukima 5-chome,

Kita-ku, Tokyo 115

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR: Rat-mouse hybridoma MR16-1 (Deposition Number)

FERM BP-5875

SCIENTIFIC DESCRIPTION AND/OR TAXONOMIC DESIGNATION 2.

The microorganism identified under 1 above was accompanied by:

a scientific description

a proposed taxonomic designation

(Mark with a cross where applicable)

RECEIPT AND ACCEPTANCE ۹.

> This International Depositary Authority accepts the microorganism identified under 1 above, which was received by it on March 13, 1997 (Date of the original deposit)1.

RECEIPT OF TRANSFER 4.

> This International Depositary Authority accepted microorganism identified under 1 above, on _ (Date of the original deposit), and accepted a request for transfer to a deposition under Budapest treaty from the original deposition, , (Transferred from FERM P on deposited 02

INTERNATIONAL DEPOSITARY AUTHORITY 5.

National Institute of Bioscience and Human-Technology

Agency of Industrial Science and Technology

Director General Michio Oishi

1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305, Japan

March 13, 1997